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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			DANIELS, MATTHEW J	
			ART UNIT	PAPER NUMBER
			1732	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/733,155

Applicant(s)

MODHA ET AL.

Examiner

Matthew J. Daniels

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-25 and 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/18/04, 11/8/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-25, and 28-37 in the reply filed on 17 January 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification/Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re*

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Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **Claims 1, 8-11, 19, 20, 22, 23, 28, 32** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 25, 33, 34, 41 of copending Application No. 10/733,172. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claims 1, 9-11, 19, 20, 23, 28, and 32 over Claims 25, 33, 34, 41 of the '172 application

Both sets of claims (independent claims 1, 19, 28 of the instant application) include the steps of dipping a former into a bath containing an elastomeric material and applying a hydrogel forming polymer to the glove.

The independent claims of the instant application are silent to crosslinking and to the active agent being incorporated and releasable from the hydrogel network. However, the step of crosslinking would have been inherent in that crosslinking is necessary to form a hydrogel coating from monomers, and is subsequently claimed in Claim 20 of the instant application. As to the active agent, the instant application claims this aspect in Claims 9-11, 23, and 32.

The '172 application is silent to the claimed thickness and to stripping without the use of antiblocking powder. However, it is well known in the art that layer thickness is a result-effective variable that the ordinary artisan finds it prima facie obvious to optimize, and the '172

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does not apply antiblocking powder as a step in the claimed process. Additionally, Claim 28 of the instant application claims the particular hydrogel compositions. However, the '172 application claims these limitations in Claims 33 and 41.

Claims 8, 22 over Claims 33 and 41 of the '172 application

Both sets of claims are directed to the same group of hydrogel-forming monomers. Therefore, by dependence on the independent claims above, the claimed limitations would have been obvious over those of the '172 application.

Claim 20 over Claim 32 of the '172 application

Both claims are directed to crosslinking agents. By dependence on the independent claims above, the claimed limitations would have been obvious over those of the '172 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Additionally, applications 10/161,546, 11/023,743, and 10/223,583 (US Published Application 2003/0118837) have been considered on the ground of nonstatutory obviousness-type double patenting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 12, 17** are rejected under 35 U.S.C. 102(b) as being anticipated by Teoh (WO 02/32475). **As to Claim 1**, Teoh teaches a method for forming an elastomeric glove, said method comprising: dipping a hand-shaped former into at least one bath containing an elastomeric material to form a substrate body (Page 3, lines 6-17 and page 6, line 1), said substrate body having an inner surface and an outer surface that define a hand-shaped cavity (inherent by use of glove former), said inner surface being positioned adjacent to said hand-shaped former (inherent that the former is coated); applying a hydrogel coating to said outer surface of said substrate body while said inner surface of said substrate body remains adjacent to said hand-shaped former (Page 6, lines 8-25), wherein said hydrogel coating has a thickness of 2-10 microns (Page 9, paragraph bridging pages 9 and 10) and thereafter, stripping the glove from said hand-shaped former without the use of an antiblocking powder (Paragraph bridging pages 10 and 11), wherein the glove is inverted so that said outer surface of said substrate body applied with said hydrogel coating is configured to face a user's hand when inserted into said hand-shaped cavity (Page 3, lines 24-25). (Page 8, lines 14-22). **As to Claim 12**, Teoh teaches applying a lubricant coating (page 6, lines 18-24). **As to Claim 17**, Teoh teaches chlorination (Page 5, lines 6-16).

6. **Claims 19 and 24** are rejected under 35 U.S.C. 102(b) as being anticipated by Teoh (WO 02/32475). **As to Claim 19**, Teoh teaches a method for forming an elastomeric article, said method comprising: dipping a former (Page 3, lines 6-17) into at least one bath containing an

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elastomeric material to form a substrate body, wherein said elastomeric material of said substrate body includes natural rubber latex (Page 5, lines 26-27), and combinations thereof, said substrate body having an inner surface and an outer surface that define a cavity (inherent in that a glove is formed), said inner surface being positioned adjacent to said former (Page 6, lines 8-25); applying a hydrogel coating and a lubricant coating to said outer surface of said substrate body while said inner surface of said substrate body remains adjacent to said former (Page 6); and thereafter, stripping the elastomeric article from said former without the use of an antiblocking powder (Paragraph bridging pages 10 and 11), wherein the elastomeric article is inverted so that said outer surface of said substrate body applied with said hydrogel coating and said lubricant coating is configured to face a user's skin when inserted into said cavity (Page 3, lines 24-25, the inverting is inherent in that a layer is coated on the outside of a former, page 6, but faces the wearer, page 3, lines 24-25). **As to Claim 24**, Teoh teaches applying a lubricant coating (page 6, lines 18-24) comprising at least a surfactant.

7. **Claims 28, 31, 33, 34, and 36** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Teoh (WO 02/32475). **As to Claim 28**, Teoh teaches a method for forming an elastomeric glove, said method comprising: dipping a hand-shaped former into at least one bath containing an elastomeric material to form a substrate body (Page 3, lines 6-17), said substrate body having an inner surface and an outer surface that define a hand-shaped cavity (inherent in that a glove is formed), said inner surface being positioned adjacent to said hand-shaped former; applying a hydrogel coating and a lubricant coating to said outer surface of said substrate body while said inner surface of said substrate

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body remains adjacent to said hand-shaped former (Page 6), wherein said hydrogel coating is formed from a monomer selected from the group consisting of hydroxyethyl acrylates, hydroxyethyl methacrylates, hydroxypropyl acrylates, derivatives thereof, and combinations thereof, (Page 8, middle) and thereafter, stripping the glove from said hand-shaped former without the use of an antiblocking powder (none is disclosed), wherein the glove is inverted so that said outer surface of said substrate body applied with said hydrogel coating is configured to face a user's hand when inserted into said hand-shaped cavity (Page 3, lines 24-25, the inverting is inherent in that a layer is coated on the outside of a former, page 6, but faces the wearer, page 3, lines 24-25).

The Examiner submits that two possible interpretations exist for this claim. In one interpretation, the hydrogel coating inherently also lubricates, and thus the limitation that a hydrogel coating and lubricant coating are applied appears to be anticipated by Teoh's teaching of a single hydrogel coating that lubricates.

In the alternative, Teoh teaches a separate lubricant coating process (Page 6, bottom, see surfactant). Although the order of steps appears to be different (Teoh strips the glove, then coats with a surfactant lubricant), it has been held that any order of performing process steps disclosed in the prior art is *prima facie* obvious in the absence of new or unexpected results. See MPEP 2144.04(IV)(C). **As to Claim 31**, Teoh teaches at least natural rubber latex (Page 5, lines 26-27). **As to Claim 33**, Teoh teaches 2-10 microns (Page 9, paragraph bridging pages 9 and 10). **As to Claim 34**, when the hydrogel lubricant of Teoh is applied, it is applied prior to stripping the glove from the former (Page 6). However, in the alternative interpretation (see the rejection of Claim 28), the claimed limitation appears to be a rearrangement of steps disclosed in the prior

art, and would have therefore been prima facie obvious in the absence of new or unexpected results. See MPEP 2144.04(IV)(C). **As to Claim 36**, Teoh teaches chlorination (Page 5, lines 6-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 2-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475). **As to Claim 2**, Teoh does not specifically teach that the substrate body includes an emulsion-based elastomeric material. However, latexes are inherently or obviously emulsion-based materials. In the alternative that latex can be applied in a method that does not require an emulsion, applying latex as an emulsion would have also been prima facie obvious. **As to Claims 3-4**, Teoh teaches natural rubber latex (Page 5, lines 26-27). **As to Claim 5**, Teoh teaches heat bonding (page 6, lines 16-24) and curing (page 8, line 21-24). Although silent to crosslinking or the polymer forming a substantially water-insoluble hydrogel network, these aspects are inherent or obvious over the teaching of curing and that the glove is washed in water after application of the hydrogel (paragraph bridging pages 8 and 9), but the hydrogel is not removed. **As to Claim 6-8**, Teoh discloses the same monomers as claimed in the instant application (page 8, lines 16-21, see hydroxyethyl methacrylate), and therefore the monomer

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having the characteristics of being water-soluble and hydrophilic would have been inherent or obvious.

9. **Claims 9-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475) in view of Holguin (US Patent Application Publication 2003/0100694). Teoh teaches the subject matter of Claim 1 above under 35 USC 102(b). **As to Claims 9 and 10**, Teoh appears to be silent to an active agent that is a drug, skin-conditioner, or a botanical agent capable of imparting a benefit to the user. However, Holguin teaches at least a drug (Par. [0102]). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Holguin into that of Teoh in order to provide a dual function as a carrier of a pharmacologically active agent and protective skin barrier. As to Claim 11, the Examiner submits that hydrogels are inherently swelled by water, and thus it appears to be an inherent or obvious aspect of Holguin's method that release of active agents upon contact with an aqueous environment would have occurred. Additionally, the Examiner submits that many of the drugs listed or described in Holguin's Paragraph [0116] would have inherently been releasable when in contact with the skin, an aqueous environment.

10. **Claims 13-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475) in view of Chen (USPN 5284607). Teoh teaches the subject matter of Claim 12 above under 35 USC 102(b). **As to Claims 13-16**, Teoh teaches a silicone lubricant (page 10, paragraph bridging pages 10 and 11) of 0.1 to 10 wt.% silicone (Page 9, lines 5-14) and a surfactant (Page 6, beginning at line 8). However, Teoh appears to be silent to a silicone

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emulsion, applied prior to stripping the glove. However, these aspects would have been prima facie obvious over Chen who teaches a silicone emulsion (Fig. 2) applied prior to stripping (Fig. 2). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Chen into that of Teoh because maintaining the form on the former would provide an easy and uniform method for coating a lubricant onto the glove, and would also provide improved donnability (4:6-8).

11. **Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475) alone or in combination with Chen (USPN 5742). Teoh teaches the subject matter of Claim 17 above under 35 USC 102(b). **As to Claim 18**, Teoh is silent to chlorinating before stripping the glove. However, it is submitted that any order of performing the steps disclosed in the prior art would have been prima facie obvious in the absence of new or unexpected results. See MPEP 2144.04 (IV)(C). In the alternative, Chen teaches that it is known to chlorinate the glove prior to removing the glove from the form (8:29-45). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Chen into that of Teoh, wherein the glove is chlorinated prior to removal, because doing so would allow the glove to remain on the former, and provide a convenient method of dipping the glove into the chlorination solution.

12. **Claims 20-22** are rejected under 35 U.S.C. 102(b) as being unpatentable over Teoh (WO 02/32475). Teoh teaches the subject matter of Claim 19 above under 35 USC 102(b). **As to Claim 20**, Teoh teaches heat bonding (page 6, lines 16-24) and curing (page 8, line 21-24).

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Although silent to crosslinking or the polymer forming a substantially water-insoluble hydrogel network, these aspects are inherent or obvious over the teaching of curing and that the glove is washed in water after application of the hydrogel (paragraph bridging pages 8 and 9). **As to Claims 21 and 22**, Teoh discloses the same monomers as claimed in the instant application (page 8, lines 16-21, see hydroxyethyl methacrylate), and therefore the monomer having the characteristics of being water-soluble and hydrophilic would have been inherent.

13. **Claim 23** is rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475) in view of Holguin (US Patent Application Publication 2003/0100694). Teoh teaches the subject matter of Claim 19 above under 35 USC 102(b). **As to Claim 23**, Teoh appears to be silent to an active agent that is a drug, skin-conditioner, or a botanical agent capable of imparting a benefit to the user. However, Holguin teaches at least a drug (Par. [0102]). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Holguin into that of Teoh in order to provide a dual function as a carrier of a pharmacologically active agent and protective skin barrier.

14. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475) alone or in combination with Chen (USPN 5742943). Teoh teaches the subject matter of Claim 19 above under 35 USC 102(b). **As to Claim 25**, Teoh is silent to chlorinating before stripping the glove. However, it is submitted that any order of performing the steps disclosed in the prior art would have been prima facie obvious in the absence of new or unexpected results. See MPEP 2144.04 (IV)(C). In the alternative, Chen teaches that it is known to chlorinate the

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glove prior to removing the glove from the form (8:29-45). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Chen into that of Teoh, wherein the glove is chlorinated prior to removal, because doing so would allow the glove to remain on the former, and provide a convenient method of dipping the glove into the chlorination solution.

15. **Claims 29 and 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475). Teoh teaches the subject matter of Claim 28 above under 35 USC 102(b), or in the alternative, under 35 USC 103(a). **As to Claim 29**, Teoh does not specifically teach that the substrate body includes an emulsion-based elastomeric material. However, latexes are inherently or obviously emulsion-based materials. In the alternative that latex can be applied in a method that does not require an emulsion, applying latex as an emulsion is common in the art and would have been prima facie obvious. **As to Claim 30**, Teoh teaches at least natural rubber latex (Page 5, lines 26-27).

16. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475) in view of Holguin (US Patent Application Publication 2003/0100694). Teoh teaches the subject matter of Claim 28 above under 35 USC 102(b), or in the alternative, under 35 USC 103(a). **As to Claim 32**, Teoh appears to be silent to an active agent that is a drug, skin-conditioner, or a botanical agent capable of imparting a benefit to the user. However, Holguin teaches at least a drug (Par. [0102]). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Holguin into that of Teoh

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in order to provide a dual function as a carrier of a pharmacologically active agent and protective skin barrier.

17. **Claims 34 and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475) in view of Chen (USPN 5284607). Teoh teaches the subject matter of Claim 28 above under 35 USC 102(b), or in the alternative, under 35 USC 103(a). **As to Claims 34 and 35**, Teoh teaches a silicone lubricant (page 10, paragraph bridging pages 10 and 11) of 0.1 to 10 wt.% silicone (Page 9, lines 5-14) and a surfactant (Page 6, beginning at line 8). However, Teoh appears to be silent to a silicone emulsion, applied prior to stripping the glove. However, these aspects would have been prima facie obvious over Chen who teaches a silicone emulsion (Fig. 2) applied prior to stripping (Fig. 2). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Chen into that of Teoh because maintaining the form on the former would provide an easy and uniform method for coating a lubricant onto the glove, and would also provide improved donnability (4:6-8).

18. **Claim 37** is rejected under 35 U.S.C. 103(a) as being unpatentable over Teoh (WO 02/32475) alone or in combination with Chen (USPN 5742943). Teoh teaches the subject matter of Claim 36 above under 35 USC 102(b), or in the alternative, under 35 USC 103(a). **As to Claim 37**, Teoh is silent to chlorinating before stripping the glove. However, it is submitted that any order of performing the steps disclosed in the prior art would have been prima facie obvious in the absence of new or unexpected results. See MPEP 2144.04 (IV)(C). In the alternative, Chen teaches that it is known to chlorinate the glove prior to removing the glove from the form

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(8:29-45). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Chen into that of Teoh, wherein the glove is chlorinated prior to removal, because doing so would allow the glove to remain on the former, and provide a convenient method of dipping the glove into the chlorination solution.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Daniels whose telephone number is (571) 272-2450. The examiner can normally be reached on Monday - Friday, 7:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJD 1/25/06



MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER